including VHD and/or pulmonary hypertension caused by the ingestion of Diet Drugs which Interneuron and Wyeth Defendants knew or should have known about.

94. Interneuron and Wyeth Defendants failed to conduct sufficient and adequate post-marketing surveillance as to the ingestion of Diet Drugs and resultant adverse events and side effects to both properly determine and quantify the risks and severity of serious side effects and take reasonable and necessary remedial action to protect the public, including Plaintiffs, from injuries being suffered by Diet Drug users which Interneuron and Wyeth Defendants knew or should have known about.

95. Defendants failed to properly and adequately warn Plaintiffs, both directly and by and through Plaintiffs' prescribing physicians, of the dangers associated with Redux such that Plaintiffs' prescribing physicians did not have available to them the body of knowledge that an adequate warning from Interneuron would have communicated to Plaintiffs' prescribing physicians.

96. As a result of Defendants' acts and omissions and other tortious conduct more fully detailed and alleged herein, Plaintiffs have sustained significant heart valve regurgitation and resultant injuries.

97. Interneuron and Wyeth Defendants undertook a course of action and marketing strategy which included advertising and promotional campaigns to aggressively promote and sell the subject drugs.

98. The product warnings in effect during the time the Diet Drugs were prescribed were non-existent or inadequate as to the need to alert prescribing physicians and consumer patients of the actual adverse health risks associated with these drugs, which risks were then known (or should have been known) to the Interneuron and Wyeth Defendants. Potential users were not

informed about the products and the serious health effects which Interneuron and Wyeth Defendants knew or should have known could result from the use of the subject drugs.

99. Wyeth Defendants and Interneuron, through their misrepresentations and omissions, created the impression and conveyed to Plaintiffs and others on whom Plaintiffs would rely, that the use of the Diet Drugs alone or in combination with phentermine was safe and had fewer adverse health and side effects than were actually associated with the Diet Drugs.

100. Interneuron and Wyeth Defendants undertook a promotional campaign that included the funding of and/or placement of numerous articles in scientific, medical and general interest magazines extolling the virtues of the Diet Drugs in order to induce widespread use of the products.

101. Interneuron and Wyeth Defendants actively encouraged, or failed to effectively discourage, the widespread prescribing of the Diet Drugs to patients that were not clinically obese.

102. Interneuron and Wyeth Defendants downplayed and understated the health hazards and risks associated with the Diet Drugs.

103. Interneuron and Wyeth Defendants failed to reveal relevant information to doctors and potential Diet Drug users including Plaintiffs and their physicians regarding the safety of the Diet Drugs.

104. Interneuron and Wyeth Defendants' through their product inserts and other documents, misrepresented a number of facts regarding the Diet Drugs, including the following:

a) The presence of adequate testing of the Diet Drugs;
b) Diet Drugs' efficacy including but not limited to the severity, frequency and discomfort of side effects and adverse health effects caused by the drugs;
c) The relative risks associated with the Diet Drugs including the prevalence of pulmonary hypertension; and

d) The relative risks associated with the Diet Drugs including the prevalence of VHD.

105. After learning of the extreme dangers associated with the Diet Drugs, Defendants did not adequately or appropriately provide information about the Diet Drugs or other relevant information to physicians in the United States, including Plaintiffs' physicians.

106. At all times relevant hereto, the Defendants' labeling on the Diet Drugs were totally inadequate to alert Plaintiffs, prescribing physicians and others of PH, VHD and/or secondary pulmonary hypertension and other dangers and risks associated with Diet Drug usage. As a result, physicians have over-prescribed the Diet Drugs to patients who were under-informed regarding the risk of secondary pulmonary hypertension or VHD associated with the drugs.

107. At all times relevant to this cause, Interneuron and Wyeth Defendants also knew or should have known of many other studies, regulatory actions and concerns, incidences of injury and/or death, concerns about the subject drugs, safety among scientists, researchers, regulators and other knowledgeable professionals, the dangers of drug combinations, meetings among pharmaceutical industry officers, executives or employees (including Defendants), internal memos and reports of health concerns regarding the subject drugs, the lack of sufficient safety studies before and during marketing of the subject drugs, the contents of Defendants' own files, plans and reports, the danger of the off-label use of medications, safety concerns about the drugs which could block or change FDA approval, regulatory actions, reports of injury and concerns about the subject drugs in Europe, case reports of pulmonary hypertension, regulatory efforts to make changes in the warning and labels required on these products and the plans and actions of Defendants to fight such changes, statements by medical professionals regarding safety concerns for the subject drugs, and adverse effects reported therefrom, the failure of Defendants to report

incidences of PH resulting from the use of the subject drugs to regulators and health care professionals, the identification of groups most at risk of injury, and many other material facts regarding the Diet Drugs which would have shown the danger and adverse health effect of using the subject drugs, but did not inform Plaintiffs, the public at large, or Plaintiffs' physicians of these material facts and risks.

108. Defendants, having undertaken the manufacture, sale, marketing, distribution and promotion of the diet drugs described herein owed a duty to provide Plaintiffs, physicians, state regulators and others upon whom it was known, or should have known, by Defendants that Plaintiffs would rely, accurate and complete information regarding the subject drug products.

109. Interneuron and Wyeth Defendants indicated to Plaintiffs, Plaintiffs' physicians, regulators and others upon whom it was known, or should have been known that each Plaintiff would rely, that the Diet Drugs were safe and effective, that the benefits of taking the subject drugs outweighed any risks and provided inaccurate safety and effectiveness information regarding its products including but not limited to the propensity to cause serious physical harm. The continuous and ongoing course of action started as early as 1993, if not earlier, and continued through repeated acts and non-disclosure every year since then, in the State of Massachusetts and in those States in which the Plaintiffs resided, were prescribed and ingested the Diet Drugs, throughout the United States, and elsewhere.

110. Interneuron's and Wyeth Defendants' fraudulent misrepresentations took the form of, among other forms, express and implied statements, publicly disseminated misinformation, misinformation provided to regulatory agencies, inadequate, incomplete and misleading warnings about the subject products, failure to disclose important safety and injury information

regarding the products while having a duty to disclose to Plaintiffs and others such information, and elaborate marketing, promotional, and advertising activities.

111. The Diet Drugs were in fact unsafe, and the use of the Diet Drugs posed an unreasonable risk of injury and death that outweighed the purported benefits of their use, such that injury was in fact caused to Plaintiffs and others.

112. Defendants, individually and jointly, failed to adequately warn Plaintiffs and those whom they knew Plaintiffs would rely of the hazards associated with the use of the Diet Drugs and failed to provide this knowledge from Plaintiffs and others. As a result of this failure to warn, Plaintiffs were caused to suffer injuries and damages.

113. The Diet Drugs were defective and unreasonably dangerous when they left the possession of Defendants in that, among other ways:

a. the Diet Drugs caused injury to the user far beyond any warned, noticed, expected or reasonable side effect or adverse reaction and when placed in the stream of commerce they contained unreasonably dangerous defects subjecting Plaintiffs to risks from expected or known usage, including bodily injury and death, which exceeded the benefits of the subject drugs;
b. when placed in the stream of commerce the Diet Drugs were defective in design and formulation, making use of the drugs more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with obesity and weight loss;
c. the Diet Drugs contained insufficient and/or ineffective warnings to alert consumers and users to the risks of injury and death by VHD and PH;
d. the Diet Drugs were insufficiently tested;
e. there were insufficient instructions on the proper use of the Diet Drugs;
f. there were inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the significant risks previously described, Defendants failed to provide adequate warnings to users and consumers, and/or their physicians, and continued to promote the sale and use of the subject drugs;
g. the Diet Drugs had not been materially altered or modified prior to the use of said drugs by Plaintiff; and
h. Defendants were in the business of distributing and selling the Diet Drugs which make the basis of this lawsuit.

114. Defendants assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged and/or sold these products in a defective condition that was unreasonably dangerous to the user or ultimate consumer of this product. Each product was expected to and did reach the user and consumer Plaintiffs without substantial change in the condition at which it was sold.

115. As a direct and legal result of the defective condition of the Diet Drugs, Plaintiffs sustained and will continue to sustain serious and permanent injuries, physical pain and suffering, impairment, disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life past and future; undergoing medical monitoring; loss of earnings and loss of the ability to earn money in the past and the future; expense of hospitalization, medical and nursing care and treatment and medical monitoring in the past and in the future; and fear and mental anguish concerning future medical problems associated with their injuries.

116. Defendants, Interneruon and Wyeth Defendants, employed, contracted, associated or otherwise engaged pharmaceutical sales persons, area account mangers, district managers, area development managers, area business directors and other representatives ("sales representatives") in furtherance of marketing, promoting, selling and/or distributing the Diet Drugs through the United States. Interneuron and Wyeth Defendants, by and through these sales representatives, provided inaccurate information or failed to provide information relating to the dangers associated with the Diet Drugs, to the consuming public, including Plaintiffs and Plaintiffs' prescribing physicians. During the course of their employment or other engagement with Interneuron and Wyeth Defendants, the sales representatives undertook the following both within the scope of their employment and at the instruction and/or direction of Interneuron and Wyeth Defendants: failed to convey adequate warnings to Plaintiffs through their prescribing

physicians; negligently distributed, marketed, advertised and/or promoted the Diet Drugs; made negligent misrepresentations regarding the safety and efficacy of the Diet Drugs; negligently failed to provide sufficient instructions to Plaintiffs and/or their prescribing physicians regarding the use of said drugs; made misrepresentations to physicians and staff, with the intent that these statements be relied upon to the detriment of patients, including Plaintiffs, including but not limited to: that the Diet Drugs were safe and effective when used as directed, and that the Diet Drugs were effective for long term weight loss. Moreover, Interneuron and Wyeth Defendants, by and through their sales representatives did not relay the true risk of serious cardiovascular and life threatening diseases such as VHD and PH.. Upon information and belief, these sales representative, armed with Plaintiffs' doctors' profile consisting of personal biographical information and periodic reports on prescribing habits, specifically discussed the importance of co-promotion of the Diet Drugs within the Interneuron and Wyeth Defendant network and with other companies and, in a coordinated fashion, implemented those discussions and agreements by bombarding prescribing physicians, including Plaintiffs' physicians, with misleading information about the Diet Drugs. As a result of the tortious actions described herein by Defendants, Interneruon's and Wyeth Defendants' sales representative agents, Interneuron and Wyeth Defendants are liable to Plaintiffs in strict products liability, negligence, fraudulent misrepresentation, fraudulent concealment, and unfair and deceptive trade practices, as well as those other actions pled in this complaint.

117. Plaintiffs were prescribed the Diet Drugs for weight loss. Plaintiffs received no warnings or statements regarding adverse effects of Diet Drug use which would warn Plaintiffs against the use of such Diet Drugs or that such Diet Drugs could cause VHD and associated injuries suffered by Plaintiffs.

COUNT I
STRICT PRODUCT LIABILITY
DEFECTIVE DESIGN

118. Plaintiffs adopt by reference all of the allegations above, each inclusive, as though fully set forth herein.

119. At all times material hereto, Defendants engaged in the business of researching, formulating, testing, developing, designing, licensing, assembling, compounding, marketing, promoting, distributing, detailing, and/or selling the Diet Drugs that were defective and unreasonably dangerous to consumers, including Plaintiffs.

120. At all times material hereto, the Diet Drugs which were researched, formulated, tested, developed, designed, licensed, assembled, compounded, marketed, promoted, distributed, detailed, and/or sold by Defendants were expected to reach, and did reach, prescribing physicians and consumers including Plaintiffs, without substantial change in the condition in which they were sold.

121. At all times material hereto, the Diet Drugs were in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, the Diet Drugs contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiffs to risks which exceeded the benefits of the drug;
b. When placed in the stream of commerce, Diet Drugs were defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with obesity and/or weight loss;
c. Diet Drugs were insufficiently tested;
d. The intended use of the drugs caused harmful side effects which outweighed any potential utility; and
e. Diet Drugs were not safe for its intended use as a weight loss drug.

122. But for the aforementioned defective and unreasonably dangerous conditions, the Diet Drugs would not have been prescribed to Plaintiffs, Plaintiffs would not have ingested the drugs, and Plaintiffs would not have sustained the injuries alleged herein.

123. As a direct and legal result of the defective condition of the Diet Drugs, Plaintiffs have sustained serious and permanent injuries including, but not limited to, injuries to the heart, pulmonary system and/or other related injuries, disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and/or nursing care and treatment, loss of earnings and loss of the ability to earn money in the future. Plaintiffs' injuries and losses are continuing in nature.

WHEREFORE, Plaintiffs demand judgment against Defendants for damages, as well as all costs of this action.

COUNT II
STRICT PRODUCT LIABILITY
FAILURE TO WARN

124. Plaintiffs adopt by reference all of the allegations above, each inclusive, as though fully set forth herein.

125. Diet Drugs were defective and unreasonably dangerous when it left the possession of Defendants in that Diet Drugs contained warnings which were misleading regarding the purported benefits associated with the drug and were inadequate and insufficient to alert physicians and consumers, such as Plaintiffs, to the dangerous risks and reactions associated with the drugs, including, but not limited to, pulmonary hypertension, heart valve disorders, and other serious and life threatening side affects, especially since any weight loss experienced was transitory. Plaintiffs' injuries and losses are continuing in nature.

126. The physicians prescribed the Diet Drugs to Plaintiffs for the intended purpose.

127. Neither the prescribing physicians nor Plaintiffs could have discovered any defect in the drug through the exercise of reasonable care.

128. Defendants are held to the level of knowledge of an expert in the field.

129. The prescribing physicians did not have substantially the same knowledge as an adequate warning from the manufacturer or distributor should have communicated to the prescribing physicians.

130. The warnings that were given by Defendants to the prescribing physicians were not adequate, accurate, or clear, and were ambiguous.

131. The limited warnings which were provided to the doctors were inappropriately placed in the fine print of the materials provided to the prescribing physicians, and Defendants failed to display those warnings prominently enough such that prescribing physicians and the consuming public would appreciate the true risks of severe and life threatening complications which had been reported in association with Diet Drugs, including, but not limited to, the pulmonary hypertension and VHD.

132. Defendants had a continuing duty to warn the prescribing physicians and Plaintiffs of the dangers associated with the Diet Drugs.

133. As a direct and legal result of Defendants' failure to warn, Plaintiffs have sustained serious and permanent injuries including, but not limited to, injuries to the heart, pulmonary system and/or other physical injuries, disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to earn money in the future. Plaintiffs' injuries and losses are continuing in nature.

WHEREFORE, Plaintiffs demand judgment against Defendants for damages, as well as all costs of this action.

COUNT III

NEGLIGENCE

134. Plaintiffs adopt by reference all of the allegations above, each inclusive, as though fully set forth herein.

135. Defendants directly or indirectly, negligently and/or defectively made, created, formulated, tested, developed, designed, licensed, assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged and/or sold the Diet Drugs throughout the United States.

136. At all times material hereto, Defendants had a duty to Plaintiffs to exercise reasonable care in the researching, formulating, testing, developing, designing, licensing, assembling, compounding, marketing, promoting, distributing, detailing, and/or selling of Diet Drugs.

137. Defendants breached that duty and was negligent in its actions and omissions toward Plaintiffs and their prescribing physicians in ways which include, but are not limited to, the following:

a. Failure to include adequate warnings with the drugs that would alert physicians to the potential risks and serious side affects of the drug;
b. Failure to adequately and properly test the drug before placing the drugs on the market;
c. Failure to conduct sufficient testing of the drugs which, if properly performed, would have shown that the drug had serious side effects, including, but not limited to, pulmonary hypertension and heart valve disorders;
d. Failure to adequately warn Plaintiffs' prescribing physicians that use of the drugs should be accompanied by a professional examination and regularly scheduled follow-up examinations so that pulmonary hypertension, heart valve disorders and other serious side effects could be avoided or detected early;
e. Failure to adequately warn Plaintiffs' prescribing physicians that use of the drugs carried a risk of pulmonary hypertension, VHD, and other serious side effects;
f. Failure to adequately warn Plaintiffs' prescribing physicians that use of the drugs carried a risk of temporary or permanent disability due to pulmonary hypertension, VHD, and other serious side effects

g. Failure to warn Plaintiffs' prescribing physicians that use of the drug carried a risk that heart surgery might become necessary to repair or replace heart valves damaged by the drug;
h. Failure to provide adequate post-marketing warnings or instructions after Defendants knew or should have known of the significant risks of pulmonary and/or VHD and/or cardiovascular injury from the use of the drug;
i. Failure to adequately warn Plaintiffs' prescribing physicians that the drug should not be prescribed for a long period of time or for use in conjunction with other weight loss drugs;
j. Failure to warn the prescribing doctors that the use of the drug should be limited to those who specialized in the treatment of obesity;
k. Failure to warn Plaintiffs' prescribing doctors that use of the drug should be limited to the morbidly obese and not used for cosmetic loss of weight;
l. Failure to warn Plaintiffs' prescribing doctors that the drug would not substantially reduce weight or reduce weight for a long period of time;
m. Failure to warn Plaintiffs' prescribing doctors that the use of the drug had not been properly studied as to safety in animals or humans; and
n. Failure to display the warnings that were provided in a manner which would properly alert the prescribing doctors as to the seriousness of the adverse events which had been reported in association with the drug.

138. Defendants knew or should have known that Diet Drugs caused unreasonably dangerous risks and serious side effects of which Plaintiffs and the prescribing physicians would not be aware.

139. But for Defendants' negligent conduct as described herein, Plaintiffs' prescribing physicians would have never prescribed Diet Drugs to Plaintiffs, Plaintiffs would not have ingested Diet Drugs and Plaintiffs would not have suffered harm from ingesting Diet Drugs.

140. As a direct and legal result of the negligence of Defendants, Plaintiffs have sustained serious and permanent injuries including, but not limited to, injuries to the heart, pulmonary system and/or other physical injuries; disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to earn money in the future. Plaintiffs' injuries and losses are continuing in nature.

WHEREFORE, Plaintiffs demand judgment against Defendants for damages, as well as all costs of this action.

COUNT IV
FRAUDULENT/NEGLIGENT MISREPRESENTATION

141. Plaintiffs adopt by reference all of the allegations above, each inclusive, as though fully set forth herein.

142. Defendants, having undertaken the manufacturing, marketing, prescription dispensing, distributing and promotion of Diet Drugs owed a duty to provide complete and accurate information regarding the drug to Plaintiffs, their physicians, and anyone else Defendants knew or should have known would ingest or prescribe the drug.

143. Defendants misrepresented material facts regarding the safety and efficacy of the Diet Drugs, and failed to inform Plaintiffs, the public and Plaintiffs' prescribing physicians these material facts.

144. Defendants fraudulently and/or negligently misrepresented to Plaintiffs, Plaintiffs' physicians, the FDA, and the general public that Diet Drugs were safe and effective, that the benefits of taking the drug outweighed any risks, and/or fraudulently and/or negligently misrepresented and concealed safety and effectiveness information regarding the product, including but not limited to the drug's propensity to cause serious physical harm. The continuous and ongoing course of action constituting fraudulent and/or negligent misrepresentation on Plaintiffs started as early as 1992, if not earlier, and continued through repeated acts and non-disclosure every year since then throughout the United States and elsewhere.

145. Diet Drugs were in fact unsafe and the use of Diet Drugs posed a risk of injury and death which outweighed the purported benefits of its use, such that injury was in fact caused to Plaintiffs and others.

146. Defendants made fraudulent and/or negligent misrepresentations regarding adverse information at a time when it knew, or should have known, that Diet Drugs had defects, dangers, and characteristics that were other than what Defendants had represented to the prescribing doctors or other dispensing entities, the FDA, and the consuming public, including Plaintiffs. Specifically, Defendants misrepresented the following:

a. It was dangerous to prescribe the Diet Drugs;
b. Diet Drugs were not intended for cosmetic weight-loss;
c. The Diet Drugs carried risks of serious adverse effects;
d. After discontinuing use, most users of the Diet Drugs would regain any weight lost as a result of its use;
e. There had been insufficient studies regarding the safety and efficacy of the Diet Drugs for use in treating weight loss;
f. That prior studies, research, reports and/or testing had been conducted linking the use of the drug or similar drugs, to serious adverse reactions, including, but not limited to, pulmonary hypertension, and VHD;
g. The fact Defendants knew, or should have known of twenty-five (25) cases of heart-valve damage reported in Belgium and/or elsewhere in Europe related to the drug or similar drugs;
h. The fact that Defendants knew or should have known of the greatly increased risk of developing pulmonary hypertension, as well as a great number of reports of the disorder related to the drugs' use;
i. the known number of cases reported to Defendants of persons who had contracted pulmonary hypertension after ingesting Diet Drugs;
j. The results of studies on animals, which revealed marked abnormalities in the cardiac and/or pulmonary tissues of these animals following diet drug ingestion;
k. The safety and efficacy of Diet Drugs in labeling, advertising, product inserts, and other materials;
l. The number of deaths that had been associated with Diet Drugs, the number of cases of heart valve damage associated with the drug, the number of cases of pulmonary hypertension associated with the drug, and the fact that the drug had been associated with pulmonary hypertension and VHD;
m. That the Diet Drugs were less effective than a placebo in achieving their intended purpose; and

n. The nature and extent of any beneficial health effect the Diet Drugs would provide the user.

147. The misrepresentations alleged above were perpetuated directly and indirectly by the Defendants.

148. The fraudulent and/or negligent misrepresentations of Defendants took the form of, among other things, express and implied statements, publicly disseminated misinformation, misinformation provided to regulatory agencies, inadequate, incomplete and misleading warnings about the subject products, failure to disclose important safety and injury information regarding the products while having a duty to disclose to Plaintiffs and others such information.

149. Defendants knew or should have known that these representations were misleading at the time they were made or omitted, and made the representations with the intent or purpose that Plaintiffs and Plaintiffs' physicians would rely on them, leading to the use of the Diet Drugs by Plaintiffs.

150. At the time of Defendants' fraudulent and/or negligent misrepresentations, Plaintiffs and Plaintiffs' physicians were unaware of the inaccuracy of the statements being made and believed them to be true.

151. Plaintiffs' physicians and Plaintiffs justifiably relied on and were induced by the misrepresentations and relied on the absence of adverse safety information in the prescription and ingestion of the Diet Drugs.

152. Defendants had a post-sale duty to warn Plaintiffs and or Plaintiffs' physicians about the potential risks and complications associated with Diet Drugs in a timely manner.

153. The misrepresentations by Defendants constitute a continuing tort.

154. Defendants made the statements and/or omissions with the intention that Plaintiffs, Plaintiffs' prescribing physicians or other dispensing entities and the consuming public would rely on such or the absence of such information in selecting Diet Drugs as a treatment for weight loss.

155. As a direct and legal result of the fraudulent and/or negligent misrepresentations of Defendants, Plaintiffs have sustained serious and permanent injuries including, but not limited to, injuries to the heart, pulmonary system and/or other physical injuries, disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, and loss of the ability to earn money in the future. Plaintiffs' injuries and losses are continuing in nature.

WHEREFORE, Plaintiffs demand judgment against Defendants for damages, as well as all costs of this action.

COUNT V
FRAUDULENT CONCEALMENT
(AGAINST DEFENDANT INTERNEURON ONLY)

156. Plaintiffs adopt by reference all of the allegations above, each inclusive, as though fully set forth herein.

157. To date, even in light of the existence of overwhelming scientific proof in the form of countless epidemiologic studies and other tests and/or studies, Defendant, Interneruon, still claims that "[b]ased on the results of studies to date, the incidence of cardiac valve abnormalities has been shown to be less than that suggested by the original FDA preliminary analysis. In general, these studies have shown either no or relatively small differences, although in some cases statistically significant, between the incidence of cardiac valve abnormalities, as defined by the FDA, among

patients who took Redux and placebo-treated patients and that the incidence of such abnormalities among Redux patients was less than previously reported estimate."

158. Furthermore, in response to law suits which have been brought against Interneuron by shareholders claiming that Interneuron misled shareholders and committed securities fraud relating to its actions associated with the approval and subsequent marketing of Redux, Interneuron has plainly yet fallaciously stated that it did not conceal known risks regarding Redux, and it has uniformly denied the causal link between Redux ingestion and the injuries referenced herein.

159. Interneuron, having undertaken the manufacturing, marketing, prescription dispensing, distributing and promotion of Redux owed a duty to provide complete and accurate information regarding the drug to Plaintiffs, their physicians, and anyone else it knew or should have known would ingest or prescribe Redux.

160. Interneuron has misrepresented material facts regarding the safety and efficacy the diet drug, and failed to inform Plaintiffs, the public and Plaintiffs' prescribing physicians these material facts, to this day.

161. The continuous and ongoing course of action constituting fraudulent concealment on Plaintiffs started as early as 1992, if not earlier, and continued through repeated acts and non-disclosure every year since then throughout the United States and elsewhere.

162. Interneuron actively concealed adverse information at a time when it knew, or should have known, that Redux had defects, dangers, and characteristics that were other than what it knew or should have known existed regarding the dangerous side effects associated with Redux.

163. The active concealment alleged were perpetuated directly and indirectly by Interneuron, and took the form of, among other things, express and implied statements, publicly disseminated misinformation, misinformation provided to regulatory agencies, inadequate, incomplete and

misleading warnings about the subject products, and a campaign of misinformation intended to convince Plaintiffs, Plaintiffs prescribing physicians, and the public that Redux is not associated with VHD or PH, and is in fact a safe and effective product.

164. Interneuron knew or should have known that these representations were false or misleading at the time they were made or omitted or concealed, and made the representations with the intent or purpose that Plaintiffs and Plaintiffs' physicians would rely on them, leading to the use of Redux by Plaintiffs, and with the specific intention that Plaintiffs rely on such misrepresentations and concealment by delaying in obtaining appropriate medical care and monitoring, in discovering their injuries associated with the use of Redux, and in discovering that such injuries were caused by the acts and omissions of Interneuron.

165. Plaintiffs and Plaintiffs' physicians had no knowledge of the information concealed and suppressed by Defendants and were unaware of the inaccuracy of any statements being made and believed them to be true.

166. Plaintiffs and Plaintiffs' physicians justifiably relied on and were induced by Interneuron's active concealment and relied on such actions, statements, and omissions.

167. Interneuron had a post-sale duty to warn Plaintiffs and or Plaintiffs' physicians about the potential risks and complications associated with Redux in a timely manner.

168. The misrepresentations and active concealment by Interneuron constitutes a continuing tort.

169. Such concealment has served to toll any applicable statute of limitations that applies to Plaintiffs' claims against Interneuron. As a direct result of the concealment, and their justified reliance thereon, Plaintiffs did not and could not have discovered their injuries caused by the ingestion of Redux, until they received an echocardiogram which indicated the presence of FDA

positive valvular heart disease and did not and could not have discovered that such injury was caused by the acts and omissions of Interneuron or their ingestion of Redux..

170. As a direct and legal result of the fraudulent concealment by Interneuron, Plaintiffs have sustained serious and permanent injuries including, but not limited to, injuries to the heart, pulmonary system and/or other physical injuries, disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, and loss of the ability to earn money in the future. Plaintiffs' injuries and losses are continuing in nature.

WHEREFORE, Plaintiffs demand judgment against Defendants Interneuron for damages. as well as all costs of this action.

PLAINTIFFS CLAIM A TRIAL BY JURY.

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DATED: March 19, 2004

COMMONWEALTH OF MASSACHUSETTS

EASTERN COUNTIES, SS.
MIDDLESEX, SS.

SUPERIOR COURT

04-1093

IN RE MASSACHUSETTS STATE COURT DIET DRUG LITIGATION
Judy Sosa; Myrna Crutcher; Roberta Tarozzi; Wendy Farris; Geraldine Hartman; Plaintiffs v. **Indevus Pharmaceuticals, Inc., F/K/A Interneuron Pharmaceuticals, Inc.; Wyeth, Inc., F/K/A American Home Products Corporation; Wyeth Pharmaceuticals, Inc F/K/A Wyeth-Ayerst Pharmaceuticals, Inc., A Division Of American Home Products Corporation; and Boehringer Ingelheim Pharmaceuticals, Inc.,** Defendants

Civil Action
No. 00-9999-G

FILED
IN THE OFFICE OF THE
CLERK OF THE COURTS
MAR 19 2004
CLERK

MOTION FOR APPOINTMENT
OF SPECIAL PROCESS SERVER

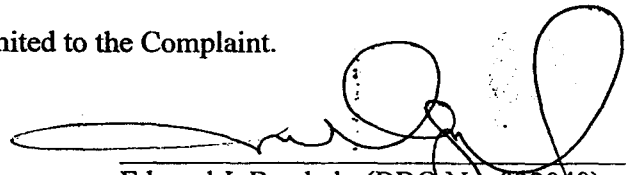
Now come the plaintiffs in the above-captioned matter and move that this Court appoint Constables Philip D. Fixman, Michael B. Fixman and Daniel P. Kochakian of Michael B. Fixman & Associates (disinterested parties and over the age of eighteen), 72 Hancock Street, P.O. Box 83, Everett, Massachusetts or a representative thereof, as

3/11/04

Houston

Attest: ASST. CLERK

Special Process Server, for the purpose of serving any and all process served in this case, including but not limited to the Complaint.



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DATED: March 19, 2004

COMMONWEALTH OF MASSACHUSETTS

EASTERN COUNTIES, SS. SUPERIOR COURT
MIDDLESEX, SS.

3

IN RE MASSACHUSETTS STATE COURT DIET DRUG LITIGATION

Civil Action No. 00-9999-G

FILED
IN THE OFFICE OF THE
CLERK OF COURTS
FOR THE COUNTY OF MIDDLESEX
APR 22 2004
Edward J. Sullivan
CLERK

Judy Sosa; Myrna Crutcher; Roberta Tarozzi; Wendy Farris; Geraldine Hartman;

Plaintiffs

v.

C.A. NO. 04-1093

Indevus Pharmaceuticals, Inc., F/K/A Interneuron Pharmaceuticals, Inc.; Wyeth, Inc., F/K/A American Home Products Corporation; Wyeth Pharmaceuticals, Inc F/K/A Wyeth-Ayerst Pharmaceuticals, Inc., A Division Of American Home Products Corporation; and Boehringer Ingelheim Pharmaceuticals, Inc.,

Defendants

FIRST AMENDED COMPLAINT

Plaintiffs, as named herein (collectively referred to as "Plaintiffs"), by and through their undersigned counsel, sue Defendants, Indevus Pharmaceuticals, Inc., f/k/a Interneuron Pharmaceuticals, Inc.; Wyeth, Inc. f/k/a American Home Products Corporation; Wyeth Pharmaceuticals, Inc. f/k/a Wyeth-Ayerst Phamaceuticals, Inc., a Division of American Home Products Corporation; and Boehringer Ingelheim Pharmaceuticals, Inc. and upon information and belief, allege as follows:

Plaintiffs' Allegations

1. Plaintiffs file this action against the named Defendants for injuries, including but not limited to valvular heart disease ("VHD"), secondary pulmonary hypertension, and other associated injuries suffered by Plaintiffs as a result of their ingestion of the defective and dangerous pharmaceutical diet drugs Redux™ and Pondimin® ("Diet Drugs") which were researched, created, formulated, tested, developed, designed, licensed, assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged and/or sold by Defendants, Indevus Pharmaceuticals, Inc., f/k/a Interneuron Pharmaceuticals, Inc. ("Interneuron" or "Defendant"); Wyeth, Inc. f/k/a American Home Products Corporation ("Wyeth Defendant" or "Defendant"); Wyeth Pharmaceuticals, Inc. f/k/a Wyeth-Ayerst Phamaceuticals, Inc. ("Wyeth Defendant" or "Defendant"); and Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer" or "Defendants") as more fully detailed herein below.

2. This action is brought on behalf of the following Plaintiffs:

a. Plaintiff **Judy Sosa** is a citizen and resident of Tallapoosa, GA suffering from VHD as a result of the ingestion, consumption and use of the Diet Drugs and is at risk of developing or is already suffering from secondary pulmonary hypertension and other related conditions as a direct and proximate result of said ingestion, consumption and use.

b. Plaintiff **Myrna Crutcher** is a citizen and resident of Richmond, KY suffering from VHD as a result of the ingestion, consumption and use of the Diet Drugs and is at risk of developing or is already suffering from secondary pulmonary hypertension and other related conditions as a direct and proximate result of said ingestion, consumption and use.

c. Plaintiff **Roberta Tarozzi** is a citizen and resident of Broomall, PA suffering from VHD as a result of the ingestion, consumption and use of the Diet Drugs and is at risk of developing

or is already suffering from secondary pulmonary hypertension and other related conditions as a direct and proximate result of said ingestion, consumption and use.

d. Plaintiff **Wendy Farris** is a citizen and resident of Bluefield, VA suffering from VHD as a result of the ingestion, consumption and use of the Diet Drugs and is at risk of developing or is already suffering from secondary pulmonary hypertension and other related conditions as a direct and proximate result of said ingestion, consumption and use.

e. Plaintiff **Geraldine Hartman** is a citizen and resident of Virginia Beach, VA suffering from VHD as a result of the ingestion, consumption and use of the Diet Drugs and is at risk of developing or is already suffering from secondary pulmonary hypertension and other related conditions as a direct and proximate result of said ingestion, consumption and use.

3. Each and every Plaintiff was prescribed and did ingest dexfenfluramine, sold under the brand name Redux™. As well, upon information and belief, some of the Plaintiffs also ingested fenfluramine, sold under both the generic name fenfluramine and the brand name Pondimin®, comprised of dexfenfluramine as its sole active ingredient.

4. Plaintiffs meet all medical criteria to qualify as intermediate and/or back-end opt-outs to the National Settlement. Specifically, Plaintiffs' echocardiograms, all of which were read and interpreted by board-certified cardiologists, demonstrate that they meet the definition of FDA positive heart valve regurgitation as defined by the National Settlement. Plaintiffs have properly exercised intermediate and/or back-end opt-out rights by completing, signing and timely submitting an opt-out form to the Settlement Court, the Trustees, and/or the Claims Administrator(s) and to the Wyeth Defendants. By filing this Complaint, Plaintiffs assert only those claims and is seeking only those damages as are permitted under the National Settlement. No other language in this Complaint shall be interpreted as Plaintiffs' intent to do otherwise. All

aspects of this action are consistent with Plaintiffs' rights as an intermediate and/or back-end opt-out from the National Class Action Settlement.

5. Each and every Plaintiff named herein has filed this lawsuit within any applicable statute of limitations period.

6. Each and every Plaintiff named herein acted with diligence in attempting to discover any injury caused by their ingestion of the Diet Drugs, including following the advise of their physicians, monitoring their symptoms, and following the recommendations of the American Medical Association, American College of Cardiology, American Heart Association, American Society of Echocardiography, United States Department of Health and Human Services, and the National Diet Drug Settlement. Such Plaintiffs did not and could not have discovered their injury until they had an echocardiogram demonstrating the presence of FDA positive valvular heart disease, and could not have brought a cause of action against any of the named Defendants, including Defendant Interneuron until such Plaintiffs discovered that any injury detected was a result of the action and/or omissions of the named Defendants, including Defendant Interneuron.

7. Any statute of limitations period which applies to the Plaintiffs' claims against Defendant Interneuron, have been tolled under the principles of class action tolling as recognized by the Appeals Court of Massachusetts in *DiCerbo v. Commissioner Of The Department Of Employment And Training*, 54 Mass.App.Ct. 128, 763 N.E.2d 566 (Mass.App.Ct. 2003), citing *American Pipe & Constr. Co. v. Utah,* 414 U.S. 538, 554, 94 S.Ct. 756, 38 L.Ed.2d 713 (1974) and *Crown, Cork & Seal Co. v. Parker,* 462 U.S. 345, 353-354, 103 S.Ct. 2392, 76 L.Ed.2d 628 (1983), as multiple class actions against Interneuron have been filed in state and federal courts across the country, bringing claims which are substantially the same as those claims brought in this lawsuit, including the class action complaint, *Doherty et al, v. Interneuron, et al,* No. 98-

0028-C, filed in Massachusetts state court in 1998 and which remained pending through the summer of 2001. Any effort by Defendant Wyeth to remove this case based on the principle of the fraudulent joinder of Defendant Interneuron is, therefore, an improvident removal, done solely to deprive Plaintiffs of their right to bring their claims in the forum of their choice.

Introduction

8. The Diet Drugs which Plaintiffs were prescribed and ingested, and which caused Plaintiffs to suffer valvular heart disease and associated injuries, were defective and unreasonably dangerous in that the Diet Drugs: were not reasonably safe for their intended use as a weight loss drugs; subjected Plaintiffs to risks which exceeded the benefits of the Diet Drugs, if any; were defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect; were more dangerous than other risks associated with obesity and/or weight loss; and were otherwise defective and unreasonably dangerous as set forth herein.

9. The defective and unreasonably dangerous Diet Drugs caused Plaintiffs to suffer from valvular heart disease and resultant injuries and damages. Valvular heart disease ("VHD") is a serious and potentially fatal disease marked by the improper backward flow or "regurgitation" of blood within in the heart's chambers and blood vessels caused by the failure of the heart's valves, which separate the heart's chambers, from properly closing. When the heart's valves fail to close sufficiently, a common result of Diet Drug ingestion, this causes the regurgitation of blood back into the chamber from which it has been pumped altering the hemodynamics within the heart. Such regurgitation is a progressive condition causing the heart to work harder to supply the body with adequate blood and oxygen. As the heart muscle is forced to over-work, physiological and morphological changes occur whereby the heart muscle becomes enlarged and distorted in shape. As a consequence, conditions and injuries suffered as a result of these and

similar Diet Drug induced changes in the heart include but are not limited to: congestive heart failure, pulmonary hypertension, valve replacement surgery, and/or death.

10. Before the Plaintiffs were prescribed and ingested the Diet Drugs which caused them to suffer VHD and associated injuries, Defendants knew or should have known that the Diet Drugs had been related to and associated with these serious and life threatening side effects. The Defendants had an obligation under the law to disclose the association between their products and VHD.

11. Due to Defendants' failure to adequately warn the FDA and doctors prescribing the Diet Drugs of the known risks of VHD, Plaintiffs' physicians were unable to inform Plaintiffs of the true risks associated with the ingestion of the Diet Drugs including VHD. These side effects were known or should have been known to Defendants at the time that they marketed the drugs to the public based on, among other things, adverse event reports, clinical studies and the medical evidence of dangerous and potentially fatal side effects from the use of the drugs in Europe and elsewhere. Defendants did not, however, conduct adequate testing to establish the safety of the drugs before marketing them nor did Defendants perform adequate post-marketing surveillance and monitoring which would have otherwise prevented Plaintiffs' injuries. Rather, the Defendants through their marketing and promotional campaigns downplayed and/or obfuscated evidence of the serious and potentially fatal side effects that consumers of these drugs could face.

Defendants

12. Defendant, Indevus Pharmaceuticals, Inc., f/k/a Interneuron Pharmaceuticals, Inc. ("Interneuron") has its principal place of business at the Ledgemont Center, 99 Hayden Avenue, Lexington, Massachusetts and is incorporated in the State of Delaware. At all times relevant hereto, Interneuron was engaged in the business of researching, formulating, testing, developing,

designing, licensing, assembling, compounding, marketing, promoting, distributing, detailing, and/or selling the pharmaceutical diet drug Redux. At all times relevant hereto, Interneuron researched, formulated, tested, developed, designed, licensed, assembled, compounded, marketed, promoted, distributed, detailed, and/or sold Redux through interstate commerce through the use of its employees and/or agents including Interneuron's field sales representative force or detailers who made direct contact with physicians including Plaintiffs' prescribing doctors. Beginning in or about 1989, Interneuron researched, created, formulated, tested, developed, designed, and/or licensed Redux. On or about November 19, 1992, Interneuron entered into a joint venture or partnership with American Cyanamid Company ("American Cyanamid" or "Wyeth Defendants"), a predecessor company to the Wyeth Defendants, and Les Laboratories Servier ("Servier") pursuant to the terms of a "Patent and Know-How Sublicense Supply Agreement" for the manufacturing, marketing, labeling, promotion and sale of Redux. On or about November 21, 1995, Defendant, Interneuron, entered into an exclusive "Contract Manufacturing Agreement" with Defendant, Boehringer, by which Boehringer agreed to manufacture, develop, test, assemble, package, label, prepare and/or supply Redux exclusively for and/or to Defendant, Interneuron, including supplying Defendant, Interneuron, with all of its requirements of Redux for ultimate sale in the United States including the State of Massachusetts. On or about June 1, 1996, Interneuron entered into a "Co-promotion Agreement" with the Wyeth Defendants which both reaffirmed the pre-existing joint venture or partnership between Interneuron and the Wyeth Defendants and provided for Interneuron to market, promote, advertise, distribute, label, detail, supply, package and/or sell Redux in consideration for the payments from Interneuron's co-promoter, Wyeth Defendants, for percentages of profit derived from sales generated by Interneuron's sales representative sales force. At all times material

hereto, Interneuron does and did business in the State of Massachusetts and researched, created, formulated, tested, developed, designed, licensed, assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged and/or sold the pharmaceutical known as Redux in interstate commerce and in the various States within which Plaintiffs were prescribed and ingested the Diet Drugs.

13. The Defendant, Wyeth, Inc., f/k/a American Home Products Corporation, is a Delaware corporation with its principal place of business at 5 Giralda Farms, Madison, New Jersey. At all times material hereto, this Defendant manufactured, supplied, packaged, labeled, detailed promoted, advertised, marketed, distributed and/or sold the pharmaceuticals known as Pondimin and Redux. A.H. Robins Company, Incorporated ("A.H. Robins") was a corporation, organized and existing under the laws of the State of Delaware, which manufactured, supplied, packaged, labeled, detailed promoted, advertised, marketed, distributed and/or sold Pondimin for many years between 1973 and 1990. A.H. Robins had its principal place of business in the State of Virginia until at least 1990, when it was acquired by American Home Products Corporation, now known as Wyeth, which company has assumed all responsibility for any liability of A.H. Robins arising from its manufacturing, supplying, packaging, labeling, detailing, promoting, advertising, marketing, distributing and/or sale of Pondimin. On or about November 19, 1992, Wyeth, Inc., through another predecessor company, American Cyanamid, whose assets and liabilities it later acquired, entered into a joint venture or partnership with Interneuron Pharmaceuticals, Inc. and Servier pursuant to the terms of a "Patent and Know-How Sublicense Supply Agreement" for the manufacturing, supplying, packaging, labeling, detailing, promoting, advertising, marketing, distributing and/or sale of Redux and at all times material was engaged in a joint venture or partnership with Interneuron Pharmaceuticals, Inc., Servier, and Boehringer Ingelheim, Inc., in

the manufacturing, supplying, packaging, labeling, detailing, promoting, advertising, marketing, distributing and/or sale of Redux. On or about June 1, 1996, this Defendant entered into a "Co-promotion Agreement" with Interneuron Pharmaceuticals, Inc. that reaffirmed the joint venture or partnership between this Defendant and Interneuron Pharmaceuticals, Inc. At all times material hereto, this Defendant does and did business in the State of Massachusetts and researched, created, formulated, tested, developed, designed, licensed, assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged and/or sold the pharmaceutical known as Pondimin and Redux in interstate commerce and in the various States within which Plaintiffs were prescribed and ingested the Diet Drugs.

14. The Defendant, Wyeth Pharmaceuticals, f/k/a Wyeth-Ayerst Laboratories, Inc., is a Delaware Corporation with its principal place of business at 555 Lancaster Avenue, St. Davids, Pennsylvania. At all times material hereto, this Defendant manufactured, supplied, packaged, labeled, detailed promoted, advertised, marketed, distributed and/or sold the pharmaceuticals known as Pondimin and Redux. A.H. Robins was a corporation, organized and existing under the laws of the State of Delaware, which manufactured, supplied, packaged, labeled, detailed promoted, advertised, marketed, distributed and/or sold Pondimin for many years between 1973 and 1990. A.H. Robins had its principal place of business in the State of Virginia until at least 1990, when it was acquired by American Home Products Corporation, now known as Wyeth, which company has assumed all responsibility for any liability of A.H. Robins arising from its manufacturing, supplying, packaging, labeling, detailing, promoting, advertising, marketing, distributing and/or sale of Pondimin. On or about November 19, 1992, Wyeth, Inc., through another predecessor company, American Cyanamid, whose assets and liabilities it later acquired, entered into a joint venture or partnership with Interneuron Pharmaceuticals, Inc. and Servier

pursuant to the terms of a "Patent and Know-How Sublicense Supply Agreement" for the manufacturing, supplying, packaging, labeling, detailing, promoting, advertising, marketing, distributing and/or sale of Redux and at all times material was engaged in a joint venture or partnership with Interneuron Pharmaceuticals, Inc., Servier, and Boehringer Ingelheim, Inc., in the manufacturing, supplying, packaging, labeling, detailing, promoting, advertising, marketing, distributing and/or sale of Redux. On or about June 1, 1996, this Defendant entered into a "Co-promotion Agreement" with Interneuron Pharmaceuticals, Inc. that reaffirmed the joint venture or partnership between this Defendant and Interneuron Pharmaceuticals, Inc. At all times material hereto, this Defendant does and did business in the State of Massachusetts and researched, created, formulated, tested, developed, designed, licensed, assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged and/or sold the pharmaceutical known as Pondimin and Redux in interstate commerce and in the various States within which Plaintiffs were prescribed and ingested the Diet Drugs.

15. The Defendant, Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer"), is a Delaware Corporation with its principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877. At all times material hereto, this Defendant was in the business of manufacturing, assembling, developing and/or supplying the pharmaceutical known as Redux. On or about November 21, 1995, Defendant, Boehringer, entered into an exclusive "Contract Manufacturing Agreement" with Defendant, Interneuron, by which Boehringer agreed to manufacture, develop, test, assemble, package, label, prepare and/or supply Redux exclusively for and/or to Defendants, Interneuron and Wyeth Defendants, including supplying Defendants Interneuron and the Wyeth Defendants, with all of its requirements of Redux for sale in the United States. At all times material hereto, Boehringer does and did business in Massachusetts

and manufactured, developed, tested, assembled, packaged, labeled, prepared and/or supplied Redux in interstate commerce and in the various States within which Plaintiffs were prescribed and ingested the Diet Drugs. Upon information and belief, the Redux ingested by Plaintiffs was manufactured, developed, tested, assembled, packaged, labeled, prepare and/or supplied by Boehringer. Though "Diet Drugs" as provided herein shall otherwise include both Redux and Pondimin, all allegations referencing "Diet Drugs" as set forth herein relating to Boehringer shall only relate to Redux.

Factual Background

16. Aminorex, discovered in 1960 by United States pharmaceutical company, McNeil Laboratories, was a drug from the same family of drugs as fenfluramine and dexfenfluramine. Aminorex was touted as a wonder weight loss drug which, like fenfluramine and dexfenfluramine, worked by increasing brain serotonin while inhibiting reuptake of serotonin.

17. Fenfluramine is made up of two "mirror image" halves or isomers: dexfenfluramine (right-handed isomer or d-isomer), the isomer which increases the release and prevents the reuptake of serotonin in the brain, thereby presumably reducing appetite, and levofenfluramine (left-handed isomer or l-isomer), which increases dopamine release but can cause the unwanted side-effect of drowsiness.

18. In 1963, Science Union & Co., an affiliate of Servier, entered into a licensing agreement with Wyeth Defendants' predecessor, A.H. Robins, giving it the right to market, promote, distribute, detail, sell or otherwise profit from the sale of fenfluramine in the United States.

19. In 1965, after securing authorization for the marketing of fenfluramine in Europe, Servier commenced the sale of products containing fenfluramine in Europe. This same year, Aminorex was introduced into the European market.

20. However, by 1967, evidence began to surface that the ingestion of Aminorex was associated with pulmonary hypertension. Over the next five years, Aminorex caused in Europe a ten-fold increase in pulmonary hypertension cases, permanent injury to patients who suffered significant oxygen deprivation, and numerous deaths. In light of the reports of Aminorex induced pulmonary hypertension, McNeil Laboratories prudently suspended its research and efforts to bring Aminorex to the United States market. By 1972, Aminorex was removed from the European market.

21. In or about 1970, during the European experience, Dr. Richard Wurtman, a faculty member of the Massachusetts Institute of Technology (MIT) and the founder of Interneuron secured a United States patent for use of fenfluramine as a diet drug. Like Aminorex, Fenfluramine was touted as a wonder weight loss drug designed to effect weight loss by increasing brain serotonin while inhibiting reuptake of serotonin. The patent and rights to market fenfluramine as an obesity drug were thereafter sub-licensed by Dr. Wurtman and/or MIT to Servier.

22. Despite the European experience, in June of 1973, fenfluramine was introduced into the United States market by A.H. Robins which sold fenfluramine under the brand name Pondimin. However, after introduction into the United States market, sales of fenfluramine languished both because of restrictions in prescribing under the Controlled Substance Act and because the fenfluramine isomer levofenfluramine caused users to become lethargic and tired when using Pondimin alone.

23. In 1977, Finnish researchers found a causal link between fenfluramine/ dexfenfluramine and heart valve lesions. Based on a study of weight-loss drugs including Aminorex and fenfluramine/dexfenfluramine and their effects on the release of serotonin, it was discovered that not only was the concentration of free serotonin in the blood vessels of the lungs caused by the weight-loss drug responsible for pulmonary hypertension, but also that the vessel wall-thickening mechanism which caused pulmonary hypertension was likely the identical mechanism which caused right-sided heart valve thickening and regurgitation in carcinoid patients.

24. Recognizing the problems in selling fenfluramine caused by the levofenfluramine isomer which caused users to become lethargic and tired, in or about 1980, Servier discovered a commercially feasible way to chemically isolate and separate the active ingredient in fenfluramine, being the right-sided d-isomer (dexfenfluramine) from the undesirable left-sided isomer (levofenfluramine) and commissioned and/or contracted Dr. Wurtman and/or MIT to further research, formulate, test, develop, design, license, assemble, compound, manufacture, market, promote, advertise, distribute, label, detail, supply, package and/or sell Redux for the United States market. This same year, MIT and/or Dr. Wurtman, secured a United States patent for use of dexfenfluramine as an obesity drug and thereafter, as with fenfluramine a decade earlier, sub-licensed the patent back to Servier.

25. On October 3, 1981, Dr. J.G. Douglas published *Pulmonary Hypertension and Fenfluramine* in the British Medical Journal. On January 25, 1986 an article entitled *Irreversible Pulmonary Hypertension after Treatment with Fenfluramine*, was published in the British Medical Journal. Defendants knew, or should have known, of the British Medical Journal

articles and how those articles related to fenfluramine and dexfenfluramine, and their propensity to cause valvular heart disease, and secondary pulmonary hypertension.

26. While the sales of Pondimin languished between 1973 and 1984, sales of Pondimin increased, however, after several studies or reports sponsored, subsidized, and/or supported by the Wyeth Defendants' predecessor, A.H. Robins, were published within the medical community. Specifically, in 1984, Dr. Michael Weintraub published *A Double-Blind Clinical Trial in Weight Control: Use of Fenfluramine and Phentermine Alone and in Combination* in the Archives of Internal Medicine. Dr. Weintraub's study was sponsored, subsidized, and/or supported by A.H. Robins (later acquired by the Wyeth Defendants). Despite noting some adverse effects associated with fenfluramine, Dr. Weintraub failed to examine the long-term safety of fenfluramine. Instead, the study focused on the short-term effectiveness of the drugs used individually, and in combination with phentermine.

27. In 1985, after securing authorization for the marketing of dexfenfluramine in Europe, Servier commenced the sale of products containing dexfenfluramine in Europe under the brand/trade names Adifax (in England) and Isomeride (in France).

28. In or about 1989, after MIT and Dr. Wurtman had researched, formulated, tested, developed, designed, licensed, assembled and compounded dexfenfluramine for several years in preparation for submitting dexfenfluramine for FDA approval and licensing for sale in the United States, Dr. Wurtman incorporated Defendant, Interneuron.

29. In or about 1990, Servier sub-licensed the rights to market, promote, distribute, detail, sell or otherwise profit from the sale of dexfenfluramine in the United States back to Interneuron.

30. On or about February 27, 1990, representatives from Interneuron, Wyeth Defendants and Servier convened to discuss "certain situations pertaining to Pondimin", including protocols

and respective responsibilities relating to adverse event reporting and safety information, during which Servier representatives Madame Derome-Tremblay and Christine Bazantay advised the Wyeth Defendants that there was a need to update the 1972 labeling for Pondimin. However, there was no change in the labeling of Pondimin between 1990 and mid-1996.

31. In September of 1990, Servier, co-licensor of both Pondimin and Redux in coordination with Interneuron and the Wyeth Defendants, completed a study regarding the effects of fenfluramine isomers on Fisher Rats which showed significant levels of focal fibrosis in the hearts of rats treated with doses of dexfenfluramine as compared with hearts of untreated rats. Defendants knew or should have known of the Fisher Rat study and how those articles related to fenfluramine and dexfenfluramine. At the very least, Interneuron and the Wyeth Defendants knew or should have known of the results of the Fisher Rat study by March 19, 1992, the date that the study was released by Servier.

32. On March 18, 1991, Interneuron, filed a petition with the DEA requesting that fenfluramine and its isomer dexfenfluramine be removed from Schedule IV and all other controls of the Controlled Substances Act (CSA) such that, among other things, both Pondimin and Redux could be dispensed and prescribed in larger quantities and over longer incremental dosage durations. Interneuron's efforts to gain the de-scheduling of both fenfluramine and dexfenfluramine, continued by using politicians and large anti-regulatory political action committees aimed at persuading both the DEA and FDA.

33. On or about October 25, 1991, Interneuron, through the assistance of Cato Research, Ltd. filed an Investigational New Drug Application with the FDA in furtherance of securing approval for Redux.